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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,249	09/28/2004	Shunichi Kuroda	12480-000067/US	4499

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HARNESS, DICKEY & PIERCE, P.L.C.
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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10509249	9/28/2004	KURODA ET AL.	12480-000067/US

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EXAMINER	
Satyanarayana R. Gudibande	
ART UNIT	**PAPER**
1654	20071017

DATE MAILED:

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Commissioner for Patents

The reply filed on 8/29/07 is not fully responsive to the prior Office Action because: Applicants in their 3rd response filed 8/29/07 to the office communication dated 6/29/07 elected "anti-human EGF receptor" stating that claims 1-5 and 22-24 remain generic with respect to this election. Applicants further state, "although the example C-4 in the specification utilize a specific 'anti-human EGF receptor' the clone 7G7B6, this antibody was identified and used for purposes of example only and should not be construed as unduly limiting the broader terminology used in the pending claims". This clearly implies that applicants are electing a genus of antibody and not a particular species of the antibody as required by the election/restriction for the prosecution purposes. Applicants have again elected "modified hepatitis B virus surface-antigen protein" (as recited in claim 8) as a species for the particle forming protein as in the previous elections on 2/8/07 and 4/23/07. Applicants traverse this election and state that claims 1-13 and 18-21 are generic to this species election. With respect to disclosed species for encapsulated substances, applicants elected "thymidine kinase (KSV1tk) gene derived from 'simple herpes virus' and applicants stated that claims 1 and 14 are generic to this election. Therefore, applicants have traversed the election/restriction and elected for the third time the genera corresponding to the cancer specific antibody genus, modified hepatitis B virus surface-antigen protein and thymidin kinase (KSV1tk) gene derived from 'simple herpes virus' in spite of the requirement that applicants elect a single disclosed species of the genus with a SEQ ID NO., or a structure corresponding to the elected species for prosecution on the merits.

Office restates the previous correspondence, office action dated 6/29/07, that contains a chronological analysis of correspondence between the office and applicants, as shown below.

"The timely submission under 37 CFR 1.129(a) filed on 4/23/07 is not fully responsive to the prior Office action because of the following chronological correspondence between applicants and the office.

Office requested a group and species election/restriction from the applicants on 1/8/07. Applicants elected group I invention with traverse on 2/8/07. Applicants also traversed the species election and elected "cancer-specific antibody" as required in for claim 2, and "modified hepatitis B virus surface-antigen protein" as required in for claim 8. Applicants have argued that mere recitation of "independent and distinct" is not sufficient to warrant a species election (page 1 I, paragraph 3 of response filed on 2/8/07). Applicants further stated that a reasonable number of sequences (ten sequences constitute a reasonable number) should be allowed to examination according to CFR 1.141 that pertains to nucleotide sequences. Applicants also allege that certain groups in USPTO have taken it upon themselves to decide that the only reasonable number is "1" in the examination of Markush group thereby eliminating the traditional Markush practice (page 12, paragraph 2 of response filed on 2/8/07). Applicants further argued that the search and examination of the claims can be made without "serious burden", examiner must examine the claims on the merits, even if they include claims to independent or distinct inventions.

Since applicants had elected genus corresponding to the "cancer-specific antibody" and genus corresponding to "modified hepatitis B virus surface-antigen protein", a bona fide non-responsive communications was sent to applicants to elect a single species

of a "cancer-specific antibody" and a single specific species of "modified hepatitis B virus surface-antigen protein" with appropriate SEQ ID NO., associated with the modified hepatitis B virus surface-antigen protein on 3/23/07. The communication also stated that the reasonable number of sequences (10 sequences) examined on the merits was only applicable nucleic acid sequences due the presence of redundancy in the genetic code and that the amino acid sequences of different protein and different peptides are distinct from each other both structurally and functionally. The office action also reiterated how the Markush group type claims are examined in the election/restriction practice especially in the species election scenario (see office action dated 3/23/07).

In their response to communication dated 3/23/07, applicants filed a response on 4/23/07. In their response filed on 4/23/07, applicants again elected "cancer-specific antibody" as the species and stated that claims 1-5 and 22-24 remain generic with respect this election. Applicants again elected "modified hepatitis B virus surface-antigen protein" as the species as recited in claim8 and reiterated that claims 1-13 and 8-21 are generic with respect to this election. Applicants further stated that the sequence listing has been supplemented to include 72 varieties of "modified hepatitis B virus surface-antigen protein" and known to those skilled in the art as encompassed by the original disclosure. Applicants further state that in the art as encompassed by the original disclosure. The Applicants further submit "that the recognition within the art that these proteins comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group". With respect to the disclosed species of encapsulated substances, applicants elected, with traverse, the 'thymidine kinase (KSVItk) gene' derived from 'simple herpes virus' as recited in claim 15. Applicants submit that at least claims 1 and 14 are generic with respect to this species election. The Applicants further submit that the Sequence Listing has been supplemented to include the 71 varieties of 'thymidine kinase (KSVItk) gene' known to those skilled in the art and would have been recognized by on skilled in the art as encompassed by the original disclosure. The Applicants further submit that the recognition within the art that these genes comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group. Applicants in support of the traverse agrees with the office that the peptides and protein sequences are distinct from one another and suggest that no logical basis has been established for distinguishing between a series of amino acids and corresponding much longer sequences of bases. Applicants therefore state that absent such a basis applicants are entitled to examination of a reasonable number of sequences. Applicants argue that "cancer-specific antibody" limitation is a functional limitation that encompasses a variety of antibodies and is not generally amenable to requested species election. Applicants points to the fact that cancer may be characterized by a range of surface proteins that will tend to change as the tumor grows and the antibodies targeting these proteins cannot therefore, be easily or realistically characterized by a single sequence. And hence applicants state that they maintain the present functional claim language sufficiently precise to define the metes and bounds of the claims to one skilled in the art. Applicants reiterate that MPEP 803 provides that where the search and examination of all the claims in an application can be made without "serious burden", the examiner must examine the claims on the merits, even if they include independent and distinct inventions.

As stated in the reply filed on 4/23/07, with respect to "modified hepatitis B virus surface-antigen protein" applicants submit that recognition within the art that these proteins comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group, and with respct to disclosed species of encapsulated substances that "thymidine kinase (KSVItk) gene" which comprise of 71 varieties of "thymidine kinase gene" are a related group be sufficient suggest that each member would be obvious in light of any other member in the group.

By agreeing with the office that peptide and proteins are typically distinct from one another and admitting that each member of the species of "modified hepatitis B virus surface-antigen protein" would be obvious in light of any other member of the group, applicants are making contradictory statements.

If applicants by their statements " [T]he Applicants further submit that the Sequence Listing has been supplemented to include the 72 varieties of "modified hepatitis B virus surface-antigen protein" known to those skilled in the art and would have been recognized by one skilled in the art as encompassed by the original disclosure. The Applicants further submit that the recognition within the art that these proteins comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group", and, "[T]he Applicants further submit that the Sequence Listing has been supplemented to include the 71 varieties of "thymidine kinase (KSVItk) gene" known to those skilled in the art and would have been recognized by one skilled in the art as encompassed by the original disclosure. The Applicants further submit that the recognition within the art that these genes comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group", mean that the species are obvious over one another, applicants should admit clearly on record that 72 varieties of"modified hepatitis B virus surface antigen" and 71 varieties of "thymidine kinase (KSVItk gene)" are not patentably distinct. Upon such an admission, the election species restriction will be withdrawn. However, if one specie of 'modified hepatitis B antigen protein" and "one species of thymidine kinase gene" is found and the invention is unpatentable over prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other species.

Absent such an admission, as per the election/restriction mailed on 1/8/07, applicants are required to elect single disclosed species of "cancer-specific antibody", single disclosed species of "modified hepatitis B virus surface antigen protein" and a single disclosed species of "encapsulated substance" for prosecution on the merit to which the claims will be restricted to if no generic claim is finally held allowable.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious

variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1. 141.

Restriction for examination purposes as stated in the office action dated 1/8/07 is proper because all these inventions listed in this action are independent or distinct for the reasons given in the office action dated 1/8/07 and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph".

Since the period for reply set forth in the prior Office action has expired, this application will become abandoned unless applicant corrects the deficiency and obtains an extension of time under 37 CFR 1.136(a).

The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. In no case may an applicant reply outside the SIX (6) MONTH statutory period or obtain an extension for more than FIVE (5) MONTHS beyond the date for reply set forth in an Office action. A fully responsive reply must be timely filed to avoid abandonment of this application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654

10/25/07
ANISH GUPTA
PRIMARY EXAMINER